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Session A. Breast cancer

A59 T-DM1 for HER2 positive advanced breast cancer: a single institution, "real life" experience

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Background: Ado-trastuzumab emtansine (T-DM1) is a novel antibody drug conjugate effective for HER2-positive metastatic breast cancer (MBC) patients (pts) previously treated with trastuzumab and taxanes.

Patients and method: Consecutive HER2 positive MBC pts treated at our institution with T-DM1 3.6 mg/kg iv every 21 days were eligible for the study. Clinicopathologic and treatment characteristics were reported. Adverse events (AEs) and severe adverse events (SAEs) were graded according to National Cancer Institute Common Terminology Criteria.

Results: Between July 2013 and May 2015, we identified 24 consecutive pts. Median age 57.5 years (range 36-80); <65 yrs 16 pts (67%), >65 yrs 8 pts (33%). Histology: ductal carcinoma 23 pts (95%), other 1 pt (5%). 17 pts (71%) had hormonal receptor (HR) positive disease and 7 (29%) HR-negative cancer; 6 pts (25%) showed an HER2 negative primary tumor, but HER2 positive on metastatic site. 6 pts (25%) showed bone metastases (mts), 8 pts (33%) visceral mts, and 10 pts (42%) both bone and visceral mts. 14 pts (58%) received a neadjuvant/adjuvant treatment. All pts were previously treated with trastuzumab and taxanes. T-DM1 was administred as first line in 1 pt (4%), as second line in 7 pts (30%), as third line in 8 pts (33%) and in 8 pts (33%) in subsequent lines. Pts received T-DM1 for a median time of 5.2 months. mPFS was 6.3 months (range 2.7-12.6). 7 pts (33%) showed a progressive disease (PD) as best response, 4 (19%) stable disease (SD), 8 (38%) partial response (PR) and 2 (10%) complete response (CR); among the 6 pts with an HER2 negative primary tumor 4 (67%) showed a PD and 2 (33%) a SD as best response. The most common toxicities reported were elevated serum concentrations of transaminases (G1-2), observed in 11 pts (46%); asthenia (G1-3) in 12 pts (50%) and nausea (G1-3) in 10 pts (42%). Thrombocytopenia (G1) was observed in 5 pts (21%). No SAEs neither cardiac events were observed. T-DM1 dose reduction due to AEs was necessary in 2 pts (8%) and no drug interruption due to toxicity was observed. No difference in AEs rate was noticed in elderly patients.

Conclusions: Our single intitution "real life" experience confirmed the very favorable toxicity profile of T-DM1, even in elderly pts. However, with the limitations of the retrospective nature of the study and the small sample size, we observed an inferior mPFS than reported previously. Interestingly the higher rate of PD in pts who showed an HER2 negative primary tumor.